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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/555,301	02/01/2006	Michael Andrew Jones	4398-474	7804
23117 7590 6429/2010 NIXON & VANDERHYE, PC 901 NORTH GLEBE ROAD, 11TH FLOOR			EXAMINER	
			BLIZZARD, CHRISTOPHER JAMES	
ARLINGTON	, VA 22203		ART UNIT	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

# Application No. Applicant(s) 10/555,301 JONES ET AL. Office Action Summary Art Unit Examiner CHRISTOPHER BLIZZARD 3771 -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS. WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status 1) Responsive to communication(s) filed on 10 March 2010. 2a) This action is FINAL. 2b) This action is non-final. 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. Disposition of Claims 4) Claim(s) 68-104 is/are pending in the application. 4a) Of the above claim(s) is/are withdrawn from consideration. 5) Claim(s) \_\_\_\_\_ is/are allowed. 6) Claim(s) 68-104 is/are rejected. 7) Claim(s) \_\_\_\_\_ is/are objected to. 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement. Application Papers 9) The specification is objected to by the Examiner. 10) The drawing(s) filed on is/are; a) accepted or b) objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abevance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. Priority under 35 U.S.C. § 119 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some \* c) None of: Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). \* See the attached detailed Office action for a list of the certified copies not received.

U.S. Patent and Trademark Office PTOL-326 (Rev. 08-06)

Attachment(s)

1) Notice of References Cited (PTO-892)

Paper No(s)/Mail Date 12/02/09, 3/10/10,

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) Information Disclosure Statement(e) (FTO/SE/DE)

Interview Summary (PTO-413)
 Paper No(s)/Mail Date.

6) Other:

5) Notice of Informal Patent Application

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## DETAILED ACTION

#### Continued Examination Under 37 CFR 1.114

- 1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 3/10/10 has been entered.
- As directed claims 1-67 have been cancelled, and claims 68-104 were added.
   Therefore this application has claims 68-104 pending.

#### Specification

3. The amendment filed 3/10/10 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: The "frame edges", "frame ribs" and "ring-shaped member".

Applicant is required to cancel the new matter in the reply to this Office Action.

## Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

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 Claims 68-74, 77-87, 90-98 and 101-104 are rejected under 35 U.S.C. 103(a) as being unpatentable over McCall (5,921,239).

6. Regarding claims 68, 82, 90 McCall discloses a mask system for treating sleep disordered breathing, comprising: a flexible shell and cushion unit (12, 14) including a cushion portion (12) forming a seal with a patient in use (fig. 1), and a shell portion (14), the shell portion including a frame-receiving channel (fig. 3, area which #20 surrounds). and an aperture centrally located on the shell portion (figs. 3 and 9, center of #44), the shell and cushion unit being an integral single piece of silicone defining an interior breathing chamber (column 5, lines 15-23 and 38-43); a rigid frame (20) including frame edges (fig .4, inner circumference) which are shaped to fit in the frame-receiving channel (fig. 3), the frame supporting the shell and cushion unit in use (fig. 1), the frame edges including frame ribs (25); A rigid ring shaped member (106) including a rear end positioned within the aperture by way of shaped surfaces (figs. 9 and 10), the ringshaped member including an annular front flange (figs. 9 and 10); a rotatable elbow (16) having a first end and a second end (fig. 3), the first end including a recess to engage wit the front flange of the ring shaped member (fig. 3); a swivel (43) provided to the second end of the rotatable elbow (fig. 3), the swivel including a first end adapted to engage with the elbow and a second end adapted to engage an air delivery conduit (18) (fig. 3); a plurality of vent holes (50) are provide on the elbow (column 3, lines 48-55); and four headgear attachments point on the frame, a pair on either side of the frame. wherein a four point headgear is attached (fig. 1) and no forehead support is provided (fig. 1). McCall does not disclose the vent holes being on the shell portion. It would

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have been obvious to one having ordinary skill in the art at the time the invention was made to relocate the vent hole from the elbow to the shell portion since it would perform equally as well and it has been held that rearranging parts of an invention involves only routine skill in the art. In re Japikse, 86 USPQ 70.

- 7. Regarding claims 72, 95, 101, 102 and 103, McCall discloses the aperture being between the headgear attachment points (fig. 1)
- 8. Regarding claims 69, 79, 83, 93 and 96, McCall does not discloses the material used in the ring-shaped member or the frame being the same, however it would have been obvious to one of ordinary skill in the art at the time of the invention to make them using the same material in order to provide the advantage of lower manufacturing costs.
- 9. Regarding claims 70 and 84, McCall does not disclose the elbow being made of polycarbonate or polypropylene. It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the elbow using polycarbonate or polypropylene, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. In re Leshin, 125 USPQ 416.
- Regarding claims 71, 85 and 97, McCall disclose the ring-shaped member being separate from the frame (fig. 3).
- Regarding claims 73, 74, 86, 87 and 98, McCall discloses four vent holes (50)
   being grouped in an array (fig. 11).
- Regarding claims 77, 91 and 104, McCall discloses upper and lower headgear attachment points, which the aperture is located between (fig. 1)

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13. Regarding claim 78, McCall discloses the shell and cushion unit providing comfort to the patient (column 5, lines 15-20), therefore it is inherent that an exterior finish is provided to increase comfort.

- Regarding claims 80 and 92, McCall discloses upper and lower headgear straps positioned above and below the ears respectively (fig. 1).
- Regarding claims 81 and 94, McCall discloses the elbow (16) having a 90 degree bend between the first and second end (fig. 3).
- Claims75, 76, 88, 89, 99 and 100 are rejected under 35 U.S.C. 103(a) as being unpatentable over McCall (5,921,239) as applied to claims 68, 82 and 96 above, and further in view of Scarberry (6,397,847).
- 17. Regarding claim Claims 75, 76, 88, 89, 99 and 100, McCall discloses the claimed mask system except for the shell and cushion unit having reinforcing ribs. Scarberry teaches a mask system (10) with reinforcing ribs (42) provided to a cushion (27), wherin the ribs have a greater thickness that adjacent portions of the cushion (figs 4 and 5). It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the mask system of McCall with reinforcing ribs as taught by Scarberry in order to provide the advantage of providing uniform compression of the cushion when in contact with the patient's face, as taught by Scarberry (column 9, lines 46-49).

### Response to Arguments

 Applicant's arguments with respect to claims 54-57, 59, 61-63, and 65-67 have been considered but are moot in view of the new ground(s) of rejection.

#### Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHRISTOPHER BLIZZARD whose telephone number is (571)270-7138. The examiner can normally be reached on Monday thru Friday, 9:00AM -5:00PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on (571)2724835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/CHRISTOPHER BLIZZARD/ Examiner, Art Unit 3771

/Steven O. Douglas/ Primary Examiner, Art Unit 3771